DENTI-CARE DENTI-FOAM TOPICAL SODIUM FLUORIDE GRAPE- sodium fluoride aerosol, foam AMD Medicam Inc.

AMD Medicom Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

10037-GR Grape Foam DentiCare Pro-Foam 2.72 % Topical Sodium Fluoride

General Information

AMD Medicom Inc.

DentiCare Pro-Foam

2.72% Topical Sodium Fluoride Foam (1.23% Fluoride Ions)

Grape

4.4 oz / 125 g

NDC 64778-0375-1

NPN 80009738

Rx Only in US

Item code 10037-GR

Indications and Directions

Indications: topical anti-caries preparation

Directions:

- 1. Following prophylaxis treatment, fill ¼ of tray with foam
- 2. To dispense, shake bottle vigorously then invert applicator 180° downward to the bottom of the tray
- 3. Insert tray, have patient bite down lightly for a minimum of 60 seconds, up to 4 minutes
- 4. Remove tray and have patient expectorate excess

Advise patient not to eat, drink or rinse for 30 minutes after the treatment

Medicinal ingredients: Fluoride ions 1.23% w/w (from 2.72% w/w sodium fluoride)

Non-Medicinal Ingredients

Water, sucralose, sodium phosphate, xylitol, betaine, pluronic, grape flavor

Warnings

KEEP OUT OF REACH OF CHILDREN. For profesional use only

Avoid spraying toward open flame. Store at room temperature. Do not expose to excessive heat over 40°C or 104°F.

Contents under pressure. Do not puncture or incinerate.

Do not use if seal is broken.

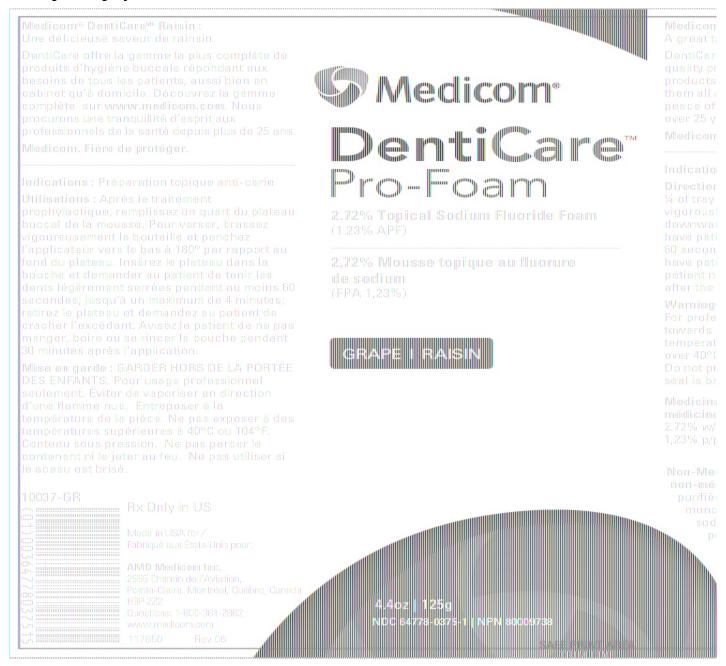
Contact Information

Made in USA for AMD Medicom Inc. 2555 Chemin de l'Aviation Pointe-Claire, Montreal, Quebec, Canada H9P 2Z2

Questions:1-800-361-2862

www.medicom.com

Principal Display Panel



sodium fluoride aerosol, foam

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:64778-0375
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8 ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	0.0272 g in 1 g

Product Characteristics	roduct Characteristics		
Color		Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:64778-0375-	12 in 1 CASE	12/0 1/20 17	12/31/2021
NDC:64778-0375-	125 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product		

Marketing Infor	rketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		04/01/2003	12/31/2021	

Labeler - AMD Medicom Inc. (256880576)

Registrant - AMD Medicom Inc. (256880576)

Revised: 12/2020 AMD Medicom Inc.